UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/691,731	10/23/2003	Cornelia Berghof	930008-2023.1	8400

20999 7590 02/03/2009

FROMMER LAWRENCE & HAUG
745 FIFTH AVENUE- 10TH FL.
NEW YORK, NY 10151

EXAMINER	
SITTON, JEHANNE SOUAYA	
ART UNIT	PAPER NUMBER
1634	
MAIL DATE	DELIVERY MODE
02/03/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/691,731	BERGHOF ET AL.	
	Examiner	Art Unit	
	Jehanne S. Sitton	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *22 and 29-33* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *22 and 29-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 9/15/2008 has been entered.

2. Currently, claims 22 and 29-33 (renumbered) are pending in the instant application. All the amendments and arguments have been thoroughly reviewed but are deemed insufficient to place this application in condition for allowance. The following rejections are either newly applied, as necessitated by amendment, or are reiterated. They constitute the complete set being presently applied to the instant Application. Response to Applicant's arguments follow. This action is Non-FINAL.

3. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

4. The New Matter rejection set forth in the previous office action is withdrawn in view of applicants agreement with the examiner's following interpretation of claim 22, made in the previous office action: Claim 22 is drawn to a set of at least 5 isolated nucleic acid molecules which are selected from the group consisting of SEQ ID NO 6, 7, 8, 9, 10, and the complement of SEQ ID NOS 6, 7, 8, 9, 10. As recited, the claim limits the set to at least 5 molecules where each is one of SEQ ID NOS 6-10 or the complement of SEQ ID NO 6-10. Accordingly, a set

where all molecules comprise the indicated SEQ ID NOS along with additional sequences on either side would not read on the recitation of claim 22. Although the claim uses the recitation of the term "comprising", this recitation modifies the "set of isolated nucleic acid **molecules**", in that additional nucleic acid molecules can exist in the set, however, the set is limited to 5 nucleic acid molecules consisting of one of the SEQ ID NOS listed (due to recitation of "selected from the group consisting of...").

Claim Rejections - 35 USC § 112

5. Claims 29, 31, and 33 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 29 is directed to a set of nucleic acid molecules which comprises at least 5 isolated nucleic acid molecules selected from SEQ ID NOS 6-10 or their complements and additionally to nucleic acids molecules from 10-250 nucleotides long which need be identical to the recited SEQ ID NOS: in as few as 10 contiguous nucleotides and which are to be used in nucleic acid hybridization or amplification to detect all representatives of *Salmonella enterica* subspecies: *enterica*, *salamae*, *arizonae*, *diarizonae*, *houtenai*, *bongori*, and *indica*. The claims encompass a large genus of nucleic acid molecules which includes nucleic acid molecules which minimally only require 10 contiguous nucleotides from one of SEQ ID NOS 1-5 or their complements and function as set forth in claim 22.

The specification discloses the sequences of SEQ ID NOS 1-10 and teaches that the sequences are identical or altered with respect to a specific region of a fragment of Salmonella typhimurium LT2 chromosome which is taught by Holmes et al in WO9500664 (the fragment is denoted as SEQ ID NO 1 in WO9500664). The disclosed structural features of SEQ ID NOS 1-10, however, do not represent a substantial portion of the claimed genus. The claimed limitation that the sequences are used to detect all representatives of *Salmonella enterica* subspecies *enterica, salamae, arizonae, diarizonae, houtenae, bongori*, and *indica* is not adequate to describe other relevant identifying characteristics of the claimed genus because the specification has not described any distinguishing characteristics of the undisclosed possible additional sequences which are encompassed by the claims that would allow the detection of all representatives of *Salmonella enterica* subspecies *enterica, salamae, arizonae, diarizonae, houtenae, bongori*, and *indica*. McClelland teaches that S. Bongori and S. Arizonae share 85% and 83% homology with coding sequences of the LT2 chromosome, illustrating that considerable variability exists between the different species. However the specification has not taught or described the identity of sequences which could be used to detect the different Salmonella species recited in the claims, nor has the specification provided an alignment of the chromosomes of the different Salmonella species recited such that the skilled artisan would be able to determine which sequences could be used to detect all representatives of *Salmonella enterica* subspecies recited.

Isolated nucleic acids selected from the group consisting of SEQ ID NOS 1-9 and 10 and complements of such meet the written description provisions of 35 USC 112, first paragraph. However, the claims are directed to and encompass variants and homologs, none of which meet

the written description provision of 35 USC 112, first paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

Response to Arguments and Declaration under 37 CFR 1.132

6. The response traverses the rejection and references and reiterates a declaration under 37 CFR 1.132 by Dr Berghof-Jaeger. The response and declaration have been thoroughly reviewed but are not persuasive to overcome the rejection. The declaration asserts that Dr. Berghof-Jaeger does not agree with the Examiner's belief about he state of the art, and that in Dr. Berghof-Jaeger's opinion, one of ordinary skill in the art would know how to align sequences and compare different strains of Salmonella compared to SEQ ID NO: 1 in Holmes to determine the appropriate sequence to choose from the claims. This argument has been thoroughly reviewed but was not found persuasive as neither the specification nor the prior art not teach the sequences the skilled artisan would need to align to determine which portions of the nucleic acids recited in the claims would function as recited. The rejection did not assert that the specification was not enabling, that is one of ordinary skill could use primers to construct sequences from different Salmonella strains and align them, however the CAFC in the University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404, 1405 held that:

To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines, Inc., 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2d at 1966.

Further, the court held that a fully described genus is one for which a person skilled in the art can "visualize or recognize the identity of the members of the genus". In contrast, the instant specification does not provide guidance regarding what structural features are responsible for the claimed function. The specification does not provide either the larger sequences from the different strains of Salmonella to determine appropriate regions of variability from which to construct appropriate sequences, nor does it describe which portions of SEQ ID NOS 1-10 are responsible for targeting different strains. Accordingly, given the limited guidance in the specification, the skilled artisan would not be able to distinguish members of the claimed genus from non members. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it, the nucleic acid itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993), and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, (claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence).

The response further asserts that Holmes disclosed a method of detect some Salmonella species by identifying a lengthy DNA nucleotide sequence and specific sequences within that DNA sequence. This argument has been thoroughly reviewed but was not found persuasive because Holmes does not teach or describe which sequences from within the claimed SEQ ID NOS are strain specific such that the skilled artisan would be able to distinguish members of the claimed genus vs non members.

The declaration asserts that it is known that an oligonucleotide does not need to be 100% complementary to a sequence to specifically bind to it, that is, oligonucleotides that are varied

with respect to a particular target sequence allow for specific detection of the target as long as the oligonucleotide does not hybridize to sequences different from the target. This argument has been thoroughly reviewed but was not found persuasive. Other than teaching the sequences of oligonucleotides consisting of SEQ ID NOS 1-10 and exemplifying a particular combination of 7 or 8 of the SEQ IDNOS that were capable of detecting all the strains recited in the claims (SEQ ID NOS 1-2 and 6-10 or SEQ ID NOS 3-5 and 6-10), the specification is silent as to which sequences can be as few as 10 contiguous nucleotides from the claimed SEQ ID NOS, but be as long as 250 nucleotides and function as required by the claims. At page 5, para 2, the declaration asserts that regarding the additional nucleic acid molecules [in claim 29], detection specificity is further on achieved if each of said additional nucleic acid molecules comprises at least a particular number of successive nucleotides matching SEQ ID NOS 1-5 and that the ordinary artisan can work the claimed invention without undue experimentation. This argument has been thoroughly reviewed but was not found persuasive. First, the reference to 'undue experimentation" is with regard to the Enablement requirement of 112/first paragraph, while the instant rejection is set forth under the description requirement of 112/first paragraph. As set forth in the MPEP 2161:

"The written description requirement is separate and distinct from the enablement requirement. In re Barker, 559 F.2d 588, 194 USPQ 470 (CCPA 1977), cert. denied, 434 U.S. 1064 (1978); Vas-Cath, Inc. v. Mahurkar, 935 F.2d 1555, 1562, 19 USPQ2d 1111, 1115 (Fed. Cir. 1991) (While acknowledging that some of its cases concerning the written description requirement and the enablement requirement are confusing, the Federal Circuit reaffirmed that under 35 U.S.C. 112, first paragraph, the written description requirement is separate and distinct from the enablement requirement and gave an example thereof.). An invention may be described without the disclosure being enabling (e.g., a chemical compound for which there is no disclosed or apparent method of making), and a disclosure could be enabling without describing the invention (e.g., a specification describing a method of making and using a paint composition made of functionally defined ingredients within broad ranges would be enabling for formulations falling within the description but would not describe any specific formulation). See In re Armbruster,

512 F.2d 676, 677, 185 USPQ 152, 153 (CCPA 1975) ("[A] specification which describes' does not necessarily also enable' one skilled in the art to make or use the claimed invention.").

Secondly, the instantly rejected claims are not directed to any specific combination of sequences and the specification does not teach which 10, 11, 12.... 18 mer, etc, from within the recited SEQ ID NOS in claim 29 would function as required by the claims.

The arguments made at page 5, paragraph 3 of the declaration, regarding the teachings of the '472 patent, which is identical to the teachings of the instant specification, have been thoroughly reviewed are not found persuasive to overcome the rejection. Further, the declaration's assertion that the '731 application is patentable distinct "yet understandable' to practice for one of ordinary skill in the art is not found persuasive. The instant specification teaches a particular combination of SEQ ID NOS that function as claimed, it does not teach which portions from within those SEQ ID NOS along with any sequences on either side, as is broadly claimed, are responsible for the claimed functionality. As such, *given the limited description in the specification*, the skilled artisan would be unable to distinguish members of the claimed genus from non members. The rejection is therefore maintained. It is noted, however, that this rejection can be overcome by removing the functional language "wherein the set is used…." from claim 22.

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 29, 31, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 29 recites "comprises at least 10 contiguous nucleotides of a sequence with a length from 10-250 nucleotides from... the group consisting of SEQ ID NOS 1-5..." However, the SEQ ID NOS listed are less than 250 nucleotides long. The metes and bounds of the claims are therefore unclear.

Double Patenting

9. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

10. Claims 22 and 29-33 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 6,706,472. Although the

conflicting claims are not identical, they are not patentably distinct from each other because they are coextensive in scope. The instantly recited claims are drawn to a set of nucleic acid molecules, comprising 5 isolated nucleic acid molecules which are directed to the sequences of SEQ ID NOS 6-10 and the complements of SEQ ID NO: 6-10 (claim 22) as well as the additional sequences recited in claim 29. The claims of '472 are directed to methods and kits for using one or more of SEQ ID NOS 1-10 and the complements of SEQ ID NOS 1-10 (SEQ ID NOS are identical). Accordingly, the claims are coextensive in scope and not patentably distinct from each other. The rejection is maintained from the previous office action.

Conclusion

11. No claims are allowed.

12. Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Jehanne Sitton whose telephone number is (571) 272-0752. The examiner can normally be reached Monday, Tuesday and Thursday from 9:00 AM to 3:00 PM.

NOTE: The examiner will be on Maternity Leave May through August 2009.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, can be reached on (571) 272-0735. The fax phone number for this Group is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547.

can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

/Jehanne Sitton/
Primary Examiner
Art Unit 1634